IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA **v.** **MURTY VEPURI,** **ASHVIN PANCHAL,** **KVK-TECH, INC.**	**CRIMINAL NO. 21-132-HB**

MEMORANDUM IN SUPPORT OF DEFENDANT KVK-TECH, INC.'S MOTION TO DISMISS THE SUPERSEDING INDICTMENT

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INTRODUCTION

This case arises out of events occurring more than ten years ago in connection with KVK Tech's (KVK) use of an active pharmaceutical ingredient (API) for a generic antihistamine drug called hydroxyzine hydrochloride (hydroxyzine). In 2010, one of KVK's API suppliers sourced API from a Belgian manufacturer (UCB) that had, in turn, obtained material for the API from a subcontractor, Dr. Reddy's Laboratories (DRL). There was not then, nor has there ever been, any allegation that the API was unsafe or ineffective. The FDA already had in its files the very information about the API the government is prosecuting defendants for allegedly failing to disclose. FDA never even issued a warning letter, and it allowed KVK to resume distributing hydroxyzine made with the API.[1]

Now, nearly a decade later, the government has brought a two-count Superseding Indictment (the "Indictment") against KVK. *See* Dkt. 4 ("Indictment"). Count One alleges that KVK, along with co-defendants Murty Vepuri and Ashvin Panchal, conspired to (a) defraud FDA; (b) introduce an "unapproved new drug" in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); and (c) make false statements in connection with the API containing material that KVK's supplier's manufacturer had sourced from DRL. Count Two alleges that KVK engaged in mail fraud in connection with a 2014 sale of $400 worth of hydroxyzine containing the API. The Court should dismiss both counts of the Indictment.

Both the conspiracy count and the mail fraud count are deficient as a matter of law because they are premised on a fundamental misunderstanding of FDA requirements applicable to the change of a supplier's API manufacturing site. The Indictment's core legal theory is that KVK

[1] Were this case to proceed to trial, KVK would show that FDA's own testing confirmed that the material from DRL was safe, effective, and fully interchangeable with the material made in-house by the Belgian manufacturer—product FDA agrees was approved.

both conspired to defraud FDA and committed mail fraud because (a) it failed to timely file the proper forms disclosing the subcontractor change, and (b) by failing to file such forms, it conspired to, and did, introduce an "unapproved new drug" into interstate commerce. But neither premise of the government's theory is correct. As a matter of law, KVK was not required to notify FDA regarding its supplier's manufacturer's use of a new subcontractor. And even if KVK violated such a requirement, as a matter of law such paperwork deficiencies did not render the hydroxyzine an "unapproved new drug." As discussed in more detail below, KVK at all times had the appropriate approval from FDA to distribute the hydroxyzine, and FDA never withdrew that approval even after learning of the alleged paperwork issues underlying this Indictment. The Indictment simply gets the law wrong by assuming both that KVK committed regulatory reporting violations and that such violations could transform KVK's approved hydroxyzine into an "unapproved new drug." Because at no time did KVK interfere with FDA's lawful regulatory functions or distribute unapproved hydroxyzine, there was no conspiracy to defraud FDA, violate the FDCA, or lie to FDA. There was also no mail fraud.

The government's fundamental legal error is not the only basis to dismiss the Indictment. Under longstanding legal principles, the conspiracy count also fails because KVK cannot be charged with conspiring only with its own agents. And the mail fraud count fails because even if the hydroxyzine were an "unapproved new drug" because material had been sourced from a subcontractor, KVK disclosed its use of that material when it voluntarily, and publicly, recalled the hydroxyzine in 2013, well before the customer identified in the Indictment paid for the product.

BACKGROUND

A. Regulatory Background

In the United States, drugs are regulated under the FDCA and its implementing regulations. Under Section 505 of the FDCA, a drug manufacturer may market a drug only after it has filed,

and FDA has approved, a new drug application (NDA) demonstrating that the drug is safe and effective for its intended use. *See* 21 U.S.C. § 355(a). For generic drugs, the application is known as an "abbreviated new drug application," or "ANDA." *See id.* § 355(j).

Among other things, ANDAs must include information regarding the composition, manufacture, and specifications for the drug and its API (*i.e.*, "drug substance"). *See* 21 C.F.R. § 314.50(d). A drug maker that manufactures both the API and the finished drug in-house generally will have all this information in its possession and can include it directly in its ANDA. *See id.* Many drug makers, however, rely on third parties to manufacture API, and those third parties may treat their manufacturing processes—*i.e.*, the recipes for their API—as confidential. *See* FDA, *Drug Master Files (DMFs)*, https://bit.ly/3Fial2t (last visited Nov. 30, 2021). In such circumstances, FDA permits the third-party API manufacturer to submit to FDA a "drug master file" (DMF) that contains all the information FDA needs about the API, *see* 21 C.F.R. § 314.420(a), and the drug maker can then incorporate the DMF by reference into its ANDA, *see id.* § 314.430(a). An ANDA is deemed to include "all data and information . . . incorporated by reference in the [ANDA], including . . . drug master files." *Id.*

Once FDA approves an ANDA, certain types of changes to the information included in the ANDA require further FDA approval before they can be implemented, other types of changes may simply require notification to FDA, and still other changes require neither approval nor notification. A regulation prescribes the paperwork each type of change requires. *See id.* § 314.70. Importantly, in all circumstances, notification to FDA is required *only* if the change at issue changes a "condition established in an approved NDA beyond the variations already provided for in the NDA." *Id.* § 314.70(a)(1)(i). FDA guidance has addressed when manufacturing sites are a "condition established in an approved NDA," *id.*, explaining that the manufacturing sites in this

category are those "owned by *the applicant* or contract sites used by *an applicant*." FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* 8 (2004) (emphases added). The guidance does not put sites used by the applicant's contract supplier's manufacturer's subcontractor in this category.

With regard to the government's allegation that KVK manufactured an unapproved new drug, there are circumstances under which FDA can withdraw approval of an ANDA, which are set forth in Section 505(e) of the FDCA. *See* 21 U.S.C. § 355(e). Section 505(e) prescribes both conditions under which FDA *must* withdraw approval and conditions under which it *may* do so. *See id.* The latter set of conditions includes "repeated[] or deliberate[]" failures to make certain "required reports," *id.*—a category that does not include reports required by 21 C.F.R. § 314.70. *See* 21 C.F.R. § 314.150(b)(1). Regardless of whether withdrawal is mandatory or optional, however, FDA generally may withdraw approval only "after due notice and opportunity for hearing to the applicant." 21 U.S.C. § 355(e). The only exception is if a drug poses "an imminent hazard to the public health." *Id.* In that case, the Secretary of Health and Human Services may "suspend the approval of [an ANDA] immediately," but must "give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing." *Id.* Unless FDA undertakes these procedures, an approval "remains effective." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973). The government does not allege that KVK's approval was ever withdrawn.

B. Factual and Procedural Background[2]

KVK is a generic pharmaceutical company located in Newtown, Pennsylvania. Indictment at 1 ¶ 1. In 2006, KVK submitted ANDAs to manufacture hydroxyzine, a prescription anti-

[2] KVK accepts the allegations in the Indictment as true for purposes of this motion to dismiss.

histamine indicated for treatment of anxiety and tension, which FDA approved the following year. *Id.* at 1 ¶ 2; *id.* at 4–5 ¶ 12. The API in hydroxyzine is hydroxyzine hydrochloride (hydroxyzine API). *Id.* at 1 ¶ 2. In relevant part, KVK's ANDAs identified Interchem, Inc. as the supplier of hydroxyzine API and UCB S.A., a Belgian company, as the manufacturer. KVK incorporated by reference UCB's DMF, and the ANDAs were approved on this basis. *See id.* at 4–5 ¶ 12.

In 2008, UCB began to subcontract production of hydroxyzine material to a Dr. Reddy's Laboratories (DRL) facility. DRL produced the material according to the specifications and processes set forth in UCB's DMF. The material DRL produced was not the finished API. UCB continued to perform testing and quality assurance procedures for the material, determine whether to release it as finished API, and ship the API under the UCB label. All of these additional testing and quality assurance steps were performed in UCB's Belgium facilities listed in the approved ANDA, and only after these steps were completed did the material become finished API that was releasable and available for sale as "UCB hydroxyzine hydrochloride," as provided for in the ANDA. KVK was not involved in UCB's decision to secure the underlying material from DRL, and was notified by UCB only after the fact. UCB also updated its DMF and notified FDA of this change to its DMF. Thus, FDA had written notice that UCB was using the material from the DRL subcontractor well before KVK distributed finished drugs containing the material.

According to the Indictment, in 2010, KVK ordered API from UCB that was made from material produced at the DRL facility, *see id.* at 7 ¶ 1, though the API was tested, released, and shipped by UCB from Belgium. KVK received the shipments in January, March, and May 2011. *Id.* at 8 ¶¶ 2, 4.

In June 2011, after KVK received those shipments, FDA issued a warning letter to DRL regarding alleged regulatory violations at its facility. *Id.* at 9 ¶ 7. The warning letter referenced

various DRL materials, but not hydroxyzine material. The following month, FDA issued an import alert prohibiting any further importation into the United States of materials from DRL. *Id.* at 9 ¶ 8. KVK's API was unaffected by this import alert because the import alert was not retroactive and KVK's API had been shipped and received before the alert went into effect. Despite the fact that the import alert did not impact hydroxyzine API that KVK had already received, UCB and KVK undertook testing to confirm that the hydroxyzine material received prior to the import alert was safe and met all applicable specifications. Following this testing, KVK distributed the hydroxyzine over the course of the next two years, from April 2011 through December 2013. *Id.* at 9–10 ¶¶ 8–9.

In June 2013, after the import alert had been lifted, FDA detained a shipment of hydroxyzine API to KVK manufactured with material originally produced in part at DRL but released by UCB as its finished API after testing. *Id.* at 10 ¶ 10. Several months later, during an inspection of KVK's facilities, FDA inspectors raised concerns about the DRL material. *See id.* at 11–12 ¶ 14. In response, in December 2013, KVK voluntarily conducted a recall of all hydroxyzine with material produced at DRL. *See* FDA, Enforcement Report – Week of Jan. 29, 2014, https://www.accessdata.fda.gov/scripts/ires/index.cfm (last visited Nov. 30, 2021) ("FDA, Enforcement Report"). Pursuant to FDA regulations that apply to voluntary recalls, KVK sent notice of the recall to all affected customers, *see* 21 C.F.R. § 7.49(a), as well as to FDA, informing them that the hydroxyzine they had received contained material from "Dr. Reddy's Laboratories in Mexico" and that they would be reimbursed for the cost of the product. *See* Exs. A–C. After receiving this voluntary recall notice, at least one of KVK's customers—AmerisourceBergen, one

of the world's largest drug wholesalers—nevertheless issued a $393.97 payment for the affected hydroxyzine.[3]

FDA subsequently conducted an inspection of KVK, where it learned nearly all the relevant facts that form the basis of the current Indictment. After that inspection, FDA decided that no warning letter or any other enforcement action was called for in connection with the alleged reporting lapse that is the basis for this criminal case, even though FDA has numerous enforcement options when it sees a basis to proceed. *See, e.g.*, 21 U.S.C. § 355(e) (setting forth circumstances when a drug's approval may be withdrawn); 21 C.F.R. § 1.980 (describing FDA's authority to detain drugs believed to be adulterated or misbranded).

Nevertheless, on June 10, 2021—nearly eleven years after UCB amended its DMF to notify FDA of its use of DRL as a subcontractor, eight years after FDA first learned that KVK had used material from DRL in its hydroxyzine, and nearly eight years after KVK voluntarily recalled all hydroxyzine in which such material was used—the government indicted KVK on two counts based on that conduct. Count One charges KVK and two associated individuals, Mr. Vepuri and Mr. Panchal, with violating 18 U.S.C. § 371 by conspiring to (1) defraud the United States by impeding FDA's work to ensure that drugs marketed in the United States are safe and effective for their intended use; and (2) commit an offense against the United States by (i) introducing, delivering for introduction, and causing the introduction or delivery for introduction of unapproved new drugs, in violation of 21 U.S.C. §§ 331(d) and 355(a); and (ii) making materially false statements and representations, and falsifying and concealing material facts, in a matter within FDA's jurisdiction, in violation of 18 U.S.C. § 1001. Indictment at 6 ¶ 16. Count One alleges that KVK violated regulatory requirements that it obtain FDA approval of its use of material from DRL; that

[3] This post-recall payment is the mailing charged in Count Two. Indictment at 16 ¶ 5.

KVK, through Vepuri and Panchal, provided FDA officials with false explanations for those violations; and that, as a result of those violations, the hydroxyzine manufactured with DRL material was an unapproved new drug. *See id.* at 7 ¶ 18; *id.* at 7–14 ¶¶ 1–19. It also alleges that Vepuri misrepresented his relationship to KVK. *See id.* at 7 ¶ 17.

Count Two charges KVK—and KVK alone—with mail fraud, in violation of 18 U.S.C. § 1341. Specifically, Count Two alleges that KVK concealed from its customers that the hydroxyzine manufactured with DRL material "was not approved by the FDA and could not be lawfully distributed in interstate commerce," and through this alleged fraud received a payment in January 2014 of $393.97 from AmerisourceBergen, a company that recorded $119 billion in revenue that year. *Id.* at 15–16 ¶¶ 4–5; *see* AmerisourceBergen Corp., Annual Report (Form 10-K) at 21 (Nov. 25, 2014), https://bit.ly/3cmVYNQ.

LEGAL STANDARD

Under Rule 12(b)(3) of the Federal Rules of Criminal Procedure, a defendant may move to dismiss an indictment for failure to state an offense. A defendant can bring such a challenge in "at least" two ways. *United States v. Stock*, 728 F.3d 287, 292 (3d Cir. 2013). First, a defendant may contend the indictment "fails to charge an essential element of the crime." *Id.* (internal quotation marks omitted). And second, a defendant may argue that "the specific facts alleged . . . fall beyond the scope of the relevant criminal statute, as a matter of statutory interpretation." *Id.* (omission in original) (internal quotation marks omitted). In assessing such arguments, a court must "accept as true the factual allegations" in the indictment. *United States v. Brennan*, 452 F. Supp. 3d 225, 231 (E.D. Pa. 2020) (internal quotation marks omitted).

ARGUMENT

I. The Indictment Should Be Dismissed Because Both Counts Turn on Alleged Regulatory Violations that Do Not Exist.

The fundamental defect in the Indictment is that both counts rest on the same flawed legal premise: that KVK allegedly violated regulatory requirements when it distributed hydroxyzine made with DRL material without notifying FDA or obtaining its approval. On this premise, the government constructs two basic theories of liability. First, the government alleges that KVK's regulatory violations rendered its hydroxyzine an unapproved new drug. *See* Indictment at 8 ¶ 5. KVK allegedly conspired to distribute this unapproved drug, leading to the charge of conspiring to violate 21 U.S.C. §§ 331(d) and 355(a), *see id.* at 6 ¶ 16(b)(1), and allegedly concealed that the drug was unapproved from its customers, leading to the mail fraud count, *see id.* at 15 ¶ 4. Second, the government alleges KVK lied to FDA about how these regulatory violations came about, *see id.* at 7 ¶ 18, leading to the charge of conspiring to defraud the United States by obstructing FDA's "lawful function[]" of regulating drugs distributed in the United States, *see id.* at 6 ¶ 16(a), as well as to the charge of conspiring to make false statements to, and conceal material facts from, FDA, *see id.* at 6 ¶ 16(b)(2).

The problem for the government is that KVK's conduct did not actually violate any regulatory requirements. Moreover, even if it did, such violations as a matter of law would not have transformed KVK's hydroxyzine into an unapproved new drug. As discussed below, without this regulatory foundation, the government cannot establish the essential elements of each offense, and therefore the allegations fall outside the scope of the relevant criminal statutes.

A. KVK Did Not Commit Any Underlying Regulatory Violation.

Both counts should be dismissed because they depend on regulatory violations that do not exist. The Indictment alleges that KVK violated "FDA regulatory requirements," *id.* at 7 ¶ 18, by

failing to seek FDA approval before using DRL material and by failing to file a field alert report after FDA issued an import alert for DRL's facility, *see id.* at 8 ¶ 2; *id.* at 9 ¶ 8; *see also* 21 C.F.R. §§ 314.80, 314.81. These alleged regulatory violations are the linchpin of the government's case. Without them, the basis for the government's allegation that KVK's hydroxyzine was an unapproved new drug crumbles, requiring dismissal of the mail fraud and conspiracy to distribute unapproved new drug charges. And without them, the government cannot establish the other objects of the alleged conspiracy—specifically, that KVK conspired to obstruct the "lawful functions" of FDA, *see* Indictment at 6 ¶ 16(a), and to falsify or conceal "material" facts, in violation of 18 U.S.C. § 1001, *see id.* at 6 ¶ 16(b)(2). Yet the government's allegation that KVK violated regulatory requirements rests on a misunderstanding of the applicable regulatory provisions. KVK did not violate any actual regulatory requirements, and therefore the government cannot establish any alleged object of the conspiracy count, or the scheme to defraud element of the mail fraud count. Accordingly, both counts should be dismissed in their entirety.

1. KVK Was Not Obligated Under 21 C.F.R. § 314.70 To Obtain FDA's Approval When It Continued to Use UCB API After UCB Sourced Material from DRL.

The government first alleges that KVK violated 21 C.F.R. § 314.70.[4] Under that regulation, KVK was required to notify FDA about "each change in each condition established in an approved NDA beyond the variations already provided for in the NDA." 21 C.F.R. § 314.70(a)(1)(i). KVK

[4] Although the Indictment does not expressly cite 21 U.S.C. § 356a or its implementing regulation, 21 C.F.R. § 314.70, these provisions are plainly the source of some of the "regulatory requirements" KVK allegedly violated. Indictment at 7 ¶ 18. In particular, these provisions set forth the circumstances when a drug maker must file a Post Approval Supplement to obtain FDA approval of a change in how it manufactures a drug. *See* 21 C.F.R. § 314.70(b); *see also* Indictment at 5 ¶ 13 (alleging that KVK was required "to file a Post Approval Supplement ('PAS') to obtain agency approval prior to distributing Hydroxyzine made with [hydroxyzine] API not approved in its ANDAs").

did not violate this requirement for three reasons: first, the switch to using DRL material did not change any "condition established" in KVK's ANDA; second, even if it did, FDA received the required notice; and third, the regulation is simply too unclear to provide parties the fair notice constitutionally required for violations to result in criminal liability.

First, the government is wrong that KVK's use of UCB API produced with material from DRL changed a condition established in its ANDA and therefore required FDA approval. *See* Indictment at 7–8 ¶¶ 1–2. The only "conditions of approval" in KVK's ANDA relating to API were (i) its sourcing of API from UCB under a cross-referenced DMF; (ii) the method of manufacturing the API; (iii) the established specifications for the API; and (iv) the testing of the API by UCB and KVK to ensure it met the approved specifications before release for manufacturing of the final drug product. Except for one change not relevant here (which KVK duly reported), none of those conditions changed. DRL produced material according to UCB's methods and specifications, and, as noted, UCB remained responsible for the final API, including quality management, quality testing, and product release decisions. Thus, because the switch to DRL's material did not entail any change to any "condition established in [KVK's] NDA," 21 C.F.R. § 314.70(a)(1)(i), KVK was not required to notify FDA of the switch.

The government, in essence, contends that by using DRL's material, KVK changed the manufacturer listed in its ANDAs from UCB to DRL. Indictment at 7 ¶ 1. But that theory is wrong. In this context, "manufacture" refers not just to initial production of the material, but to the testing and quality assurance necessary to ensure that the API meets approved specifications. *See* 21 C.F.R. § 207.1 ("Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs for another registered establishment's drug."); *id.* § 210.3(b)(12) (defining "manufacture"

to include "testing[] and quality control of drug products"); FDA, *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Guidance for Industry* 1 (Sept. 2016) (defining "manufacturing" to include "quality control" and "release" of APIs). UCB continued to perform those functions throughout the relevant time, including for the material produced by DRL, and therefore remained the manufacturer of record of the API.

Longstanding FDA guidance underscores this point. It provides that FDA's Center for Drug Evaluation and Research (CDER) "must be notified when a manufacturer changes to a manufacturing site that is different from those specified in the approved application . . . . Sites include those owned by the applicant or contract sites used by an applicant." FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA*, *supra*, at 8. The first sentence creates a reporting obligation for a "manufacturing site" change by a "manufacturer." Here, KVK changed nothing; it was not the API "manufacturer." Instead, it was UCB, the API "manufacturer," that shifted to a subcontractor. The second sentence also imposes no requirement on KVK, as KVK (*i.e.*, the "applicant") neither "owned" nor had a "contract" with DRL. Nor was DRL "used" by KVK, as DRL was under contract with UCB. FDA's guidance links the word "used" to the words "contract site," indicating that it refers to an applicant who has a legal right to use the site. It would stretch the word "use" beyond its plain meaning to suggest that an applicant "uses" a manufacturing site that it does not own or contract to use. FDA's guidance could have required that "*an applicant* must notify CDER when *any establishment involved in the manufacture* of an approved drug or API changes to a manufacturing site that is different from those specified in the approved application." But it did not. Instead, the guidance FDA actually wrote indicates that no filing was required in this situation.

Second, even if FDA notification were required, FDA received it. It is undisputed that, prior to KVK's distribution of hydroxyzine containing the DRL material, UCB notified FDA of its subcontracting to DRL by filing an amendment to its DMF describing the formulation activities that would occur at DRL. KVK's ANDAs incorporated UCB's DMF by reference, which under FDA regulations meant that the ANDAs incorporated all the information in that DMF. *See* 21 C.F.R. § 314.430(a) (providing that an ANDA "includes all data and information . . . incorporated by reference in the . . . [ANDA], including . . . drug master files"). The ANDAs also included a Letter of Access from UCB in which UCB "agree[d] to inform KVK-Tech, Inc. and the FDA of any change in the content of the complete Drug Master File." FDA thus had advance notice that DRL was producing material pursuant to UCB's DMF and that KVK was using it—and, notably, FDA never raised any concerns in response. Having already received timely notice from one party, the government is not entitled to wait almost a decade and then accuse another party of a crime for not filing what is essentially a duplicate notice.

Third, the byzantine regulatory scheme undergirding the government's charges is simply too vague and unclear to serve as a basis for criminal liability. It is well-established that "agencies should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires.'" *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (alteration in original). "[F]air warning requires that government agencies communicate their interpretation of their own regulations with 'ascertainable certainty' before subjecting private parties to punishment under that interpretation." *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021). This is especially true when regulatory violations would result in criminal liability. Under the rule of lenity, courts interpret ambiguous criminal statutes and regulations in the defendant's favor so as to ensure that

an agency "clearly communicated its policies before a private party may be sanctioned—much less criminally prosecuted—for violating them." *Id.*

FDA, however, has conceded that 21 C.F.R. § 314.70 falls far short of providing fair warning regarding what constitutes a "condition established" in an ANDA. In 2015, it published draft guidance "to address the lack of clarity with respect to what chemistry, manufacturing, and controls (CMC) information in a marketing application constitutes an established condition . . . that, if changed following approval, requires reporting to FDA" under § 314.70. FDA, *Draft Guidance, Established Conditions: Reportable CMC Changes for Approved Drugs and Biologic Products: Guidance for Industry* 1 (May 2015). The draft guidance acknowledged that "there has not been a common understanding of the meaning of the phrase[] 'each condition established in an approved application,'" *id.* at 2, and that "[t]he practical meaning of th[is] phrase[] has been described in many ways," *id.* As a result, FDA concluded "there is confusion regarding which elements of an application are considered to be established conditions," which could lead, among other things, to manufacturers not reporting "changes that should have been reported to FDA." *Id.* at 3. This backdrop of "confusion," "lack of clarity," and differing understandings of what constitutes established conditions cannot support criminal charges predicated on the idea that KVK's supplier's manufacturer's decision to subcontract production of material for API changed a "condition established" in KVK's ANDAs.

Furthermore, even if there is a change to a condition established in an ANDA, the provisions governing how notification should be made to FDA, and whether the change can be implemented without pre-approval from FDA, are themselves incurably vague. *See* 21 C.F.R. § 314.70(a)–(d). Under 21 U.S.C. § 356a(c), only "major changes" require that a supplement be filed and approved by FDA before implementation of the changes. A major change is defined as

one that is determined to have a "substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug." 21 U.S.C. § 356a(c)(2); 21 C.F.R. § 314.70(b). But only a few examples of such changes are provided by the governing provisions. Further, the statute contemplates that other types of changes may or may not require some form of supplement or notification. *See* 21 U.S.C. § 356a(d). The implementing regulation fills in the gap left by the statute and creates reporting obligations for two other types of non-major changes and provides standards for each. Specifically, a change to an established condition that is a "moderate" change, meaning a change "that has a moderate potential to have an adverse effect on the identity, strength, quality, purity or potency of the drug product," requires the filing of a submission to FDA 30 days prior to distribution of the drug product made using the change (a "CBE 30" submission), and the change can be implemented pending approval once 30 days have elapsed unless FDA notifies the applicant otherwise. 21 C.F.R. § 314.70(c). Finally, a change is considered "minor" and does not require pre-approval submission to FDA if the change has a "minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency" of the final drug product. *See id.* § 314.70(d). Minor changes need only be described in the final drug product annual report. *Id.* Under the regulation, a change that has no potential at all to have an adverse effect on the final drug product need not even be reported in an annual report. *Id.*

Because the standards regarding what constitutes a "major," "moderate," or "minimal" potential to cause an adverse impact on a final drug product are vague and confusing, and the examples provided in the regulation do not cover nearly enough kinds of changes, FDA issued initial guidance to further clarify the regulation in 2004. *See* FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA*, *supra*, at 8. However, this guidance was insufficient to put industry

on notice of what the governing statute and regulations required, and the agency continued to issue guidance. In light of the vague and confusing nature of these obligations, it is appropriate and fitting that Congress never legislated a prohibited act in 21 U.S.C. § 331 tied directly to a violation of 21 U.S.C. § 356a or its implementing regulation, 21 C.F.R. § 314.70.

Ultimately, because FDA did not "communicate [its] interpretation of [§ 314.70] with 'ascertainable certainty,'" *Harra*, 985 F.3d at 213, the government cannot subject KVK to punishment under that interpretation. FDA's failure to provide fair warning of what conduct violates § 314.70 provides an additional and independent ground for dismissing both counts.

2. KVK Was Not Obligated to File a Field Alert Report Under 21 C.F.R. § 314.81.

The government's allegation that KVK was required to file a field alert report under 21 U.S.C. § 314.81 is also wrong as a matter of law. *See* Indictment at 9 ¶ 8. That provision required submission of a field alert report upon learning of information concerning (1) "any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article"; (2) "any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product"; or (3) "any failure of one or more distributed batches of the drug product to meet the specification established for it in the application." 21 C.F.R. § 314.81(b)(1).

No such conditions are alleged here. The Indictment does not allege that the drug was "mistaken for" another drug, that there was "any bacteriological contamination, or any significant chemical, physical, or other change or deterioration," or that there was any failure to meet a specification. And, tellingly, the government did not charge KVK with conspiring to distribute, or distributing, *adulterated* drugs. This charging decision tacitly concedes that the hydroxyzine manufactured with DRL material was identical in all material respects to that manufactured with

UCB material, such that no field alert report under § 314.81 was required—a point the government also acknowledged years ago, when in 2014 it accepted KVK's supplemental filing for the DRL material, confirming that the DRL and UCB products are interchangeable.

B. Any Failure to Obtain FDA Approval for DRL Material Did Not Transform KVK's Hydroxyzine into an Unapproved New Drug.

The charges of mail fraud and conspiracy to distribute an unapproved new drug fail for the additional reason that both charges rest on a second flawed premise: that the defendants' alleged conduct transformed KVK's hydroxyzine into an unapproved new drug.

First, consider the charged conspiracy to distribute an unapproved new drug. To establish a conspiracy in violation of 18 U.S.C. § 371, the government must prove, *inter alia*, "the existence of an agreement to achieve an unlawful objective." *United States v. Rigas*, 605 F.3d 194, 206 (3d Cir. 2010) (en banc) (internal quotation marks omitted).[5] Here, the alleged unlawful objective was distributing an unapproved new drug, in violation of 21 U.S.C. §§ 331(d) and 355(a). *See* Indictment at 6 ¶ 16(b)(1). As set forth in the Indictment, the government's theory is that KVK and its co-defendants violated regulatory requirements by using DRL material without required FDA approval, and that those regulatory violations meant that the ANDAs approval governing KVK's hydroxyzine evaporated such that the drug could no longer be lawfully distributed. *See id.* at 8–9 ¶¶ 2, 5, 6, 8.

This theory, however, rests on a basic legal error. It assumes, incorrectly, that KVK's alleged failures to make the filings required by 21 C.F.R. § 314.70 transformed an approved drug into an unapproved one. *See id.* But that is wrong. Throughout the relevant period (and to this day),

[5] The other elements of a § 371 violation are "the defendant's knowing and voluntary participation in the conspiracy" and "the commission of an overt act in furtherance of the conspiracy." *Rigas*, 605 F.3d at 206.

KVK's ANDAs for hydroxyzine remained in effect. FDA could have sought to withdraw the ANDAs for the drug, but did not. Therefore KVK did not violate 21 U.S.C. §§ 331(d) or 355(a) by distributing the drug.

Section 505 of the FDCA expressly addresses when and how FDA may withdraw approval for a drug such that further marketing of the drug is prohibited. *See* 21 U.S.C. § 355(e). In particular, it provides that except in cases of "imminent hazard to the public health," FDA may withdraw approval only after "due notice and opportunity for hearing to the applicant." *Id.*[6] This process is exclusive. As the Supreme Court has recognized, "[§ 355(e)] leads to the conclusion that an NDA remains effective unless it is suspended." *Weinberger*, 412 U.S. at 633.

Here, FDA never suspended KVK's three approved ANDAs for its three dosage forms of hydroxyzine (or even initiated the process for doing so), and KVK therefore never lost its authorization to market hydroxyzine pursuant to those ANDAs. *See, e.g.*, FDA, *Product Details for ANDA 040786, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, https://bit.ly/3bXCQ8Q (last visited Nov. 30, 2021) (showing that KVK has held valid ANDAs for hydroxyzine since 2007);[7] *see also Bell v. Boehringer Ingelheim Pharms., Inc.*, No. 17-1153, 2018 WL 2447788, at *1 (W.D. Pa. May 31, 2018) (taking judicial notice of the Orange Book, a "public[ly] available list of drugs which have been approved [by FDA] for safety and effectiveness" (internal quotation marks omitted)); *United States v. Gimbel*, 632 F. Supp. 713, 722 n.12 (E.D. Wis. 1984) (on motion to dismiss indictment, taking judicial notice of document

[6] The Secretary of Health and Human Services is authorized to immediately suspend approval of a drug if he "finds that there is an imminent hazard to the public health," but he must then "give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection." 21 U.S.C. § 355(e).

[7] Although KVK submitted separate ANDAs for each of the three dosage forms of hydroxyzine (10 mg, 25 mg, and 50 mg), *see* Indictment at 4–5 ¶ 12, the Orange Book now lists all three dosage forms under ANDA 040786.

"not included on the face of the Indictment," but "referred to there throughout"); *United States v. Lamont*, 236 F.2d 312, 316-17 (2d Cir. 1956) ("It is elementary law that pleadings, both criminal and civil, must be read in the light of the facts of which the court takes judicial notice."). Thus, as a matter of law, the government's theory that KVK's hydroxyzine was an unapproved drug that "could not be lawfully distributed in interstate commerce," Indictment at 15 ¶ 4, fails. So too does its allegation that the defendants in this case conspired to introduce unapproved new drugs into commerce. *Id.* at 6 ¶ 16(b)(1). Throughout the relevant period, "an approval of an application filed pursuant to [§ 355(j)] [was] effective with respect to" KVK's hydroxyzine, and therefore KVK was authorized to introduce that drug into interstate commerce. 21 U.S.C. § 355(a).

Furthermore, the government's view that violations of 21 C.F.R. § 314.70 could, on their own, vitiate an approval is foreclosed by both the FDCA and FDA regulations. In addition to providing specific procedures FDA must follow to withdraw an approval, Section 505(e) sets forth the specific grounds authorizing such action. *See id.* § 355(e); *see also* 21 C.F.R. § 314.150 (listing such grounds). Notably, it specifically provides that FDA may withdraw approval for failure to "make required reports, in accordance with a regulation or order under [§ 355(k)]," but does not mention filings required by other provisions, such as 21 U.S.C. § 356a, the provision § 314.70 implements. Thus, under the "venerable canon of statutory construction" that "where a specific list is set forth, it is presumed that items not on the list have been excluded," *Lewis v. Alexander*, 685 F.3d 325, 347 (3d Cir. 2012), the government may not expand the grounds for withdrawal of an approval to include a violation of § 314.70.[8]

[8] By the same token, the failure to file applications regarding manufacturing changes pursuant to 21 U.S.C. § 356a and 21 C.F.R. § 314.70 is not listed among the prohibited acts in 21 U.S.C. § 331 that can trigger criminal or civil liability under 21 U.S.C. § 333.

FDA's own regulations reflect this limitation. The regulations requiring reports pursuant to § 355(k) specifically provide that "[i]f an applicant fails to . . . make reports required under this section, FDA may withdraw approval of the application *and, thus, prohibit continued marketing of the drug product that is the subject of the application*." 21 C.F.R. §§ 314.80(k) (emphasis added); *see id.* § 314.81. By contrast, § 314.70 contains neither this language nor anything comparable. FDA's omission of such language from § 314.70 recognizes that violations of that provision cannot, on their own, result in any prohibition on further marketing of a drug. *See Collins v. Yellen*, 141 S. Ct. 1761, 1782 (2021); *see also Jimenez-Rodriguez v. Garland*, 996 F.3d 190, 196 (4th Cir. 2021) (recognizing that the *expressio unius* canon may apply to regulations as well as statutes). Moreover, even violations of §§ 314.80 and 314.81 do not automatically result in withdrawal of approval, those provisions specify that FDA "may" withdraw approval for violations, *see Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 346 (2005) ("The word 'may' customarily connotes discretion."), and to do so FDA still must follow the procedures set forth in Section 505(e) and corresponding regulations. *See* 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.150(b), 314.152.

The government's view of § 314.70 is also irrational as a practical matter. Under Section 505(e), FDA *must* withdraw approval only if it finds that a drug is unsafe or ineffective, or that the application contained a material misrepresentation, *see* 21 U.S.C. § 355(e), and even then may do so only "after due notice and opportunity for hearing to the applicant," *id.* Yet under the government's view, any paperwork violation under § 314.70 *automatically* renders a drug an unapproved new drug, without any further procedural safeguards and irrespective of any safety concerns. This makes no sense.

Thus, even if the government were correct that KVK violated § 314.70 by using DRL material without providing proper notification to FDA—and it is not, *see supra* Section I.A.1—the government's theory that this violation transformed hydroxyzine into an unapproved new drug is wrong as a matter of law. Because FDA never withdrew approval of KVK's hydroxyzine ANDAs, the ANDAs "remain[ed] effective" and KVK did not violate § 355(a) by marketing the drug. *Weinberger*, 412 U.S. at 633. The government therefore cannot establish that the object of the alleged conspiracy—distributing hydroxyzine—was unlawful. This prong of the conspiracy charge must therefore be dismissed. *See* Indictment at 6 ¶ 16(b)(1).

The government's misunderstanding of the applicable regulatory scheme is also fatal to the mail fraud count. An essential element of mail fraud is a scheme to defraud,[9] which requires "fraudulent misrepresentations or omissions reasonably calculated to deceive persons of ordinary prudence and comprehension." *United States v. Pearlstein*, 576 F.2d 531, 535 (3d Cir. 1978). Here, the alleged fraudulent omission is that KVK allegedly concealed "that the drug as manufactured was not approved by the FDA and could not be lawfully distributed in interstate commerce." Indictment at 15 ¶ 4. For the reasons set forth above, however, KVK *could* lawfully distribute hydroxyzine in interstate commerce, and it therefore concealed nothing. Because the facts, as alleged, fall outside the scope of what the mail fraud statute prohibits, the mail fraud count must also be dismissed.

[9] The elements of mail fraud are (1) a scheme to defraud; (2) participation by the defendant in the scheme with the specific intent to defraud; and (3) use of the mails in furtherance of the scheme. *United States v. Hannigan*, 27 F.3d 890, 892 (3d Cir. 1994). To establish a scheme to defraud, a misrepresentation or omission must relate to material facts. *See Neder v. United States*, 527 U.S. 1, 25 (1999).

II. KVK Cannot Be Charged with Conspiring with Its Own Agents.

The conspiracy charge against KVK must also be dismissed because it alleges a conspiracy among only KVK and its purported agents, Vepuri and Panchal. It is well-established, however, that "a corporation cannot conspire with itself," *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1134 (3d Cir. 1995) (internal quotation marks omitted), and thus conspiracy allegations fail where they allege simply that the corporation has "conspire[d] with one who acts as its agent,"[10] *Gen. Refractories Co. v. Fireman's Fund Ins. Co.*, 337 F.3d 297, 313 (3d Cir. 2003); *accord, e.g.*, *United States v. Basroon*, 38 F. App'x 772, 781 (3d Cir. 2002) (per curiam) (affirming mail and wire fraud convictions where jury was instructed that "[a] corporation cannot conspire with its own officers and employees"); *United States v. Anderson*, 368 F. Supp. 1253, 1259 (D. Md. 1973) ("[A] *corporation* cannot conspire with its employees and officers since a corporation can only act through its agents."). Here, according to the Indictment, Vepuri and Panchal were, at all relevant times, agents of KVK. *See, e.g.*, Indictment at 7 ¶ 18 (alleging that KVK was acting "through defendants Murty Vepuri and Ashvin Panchal" (capitalization altered)). Therefore, as a matter of law, KVK could not conspire with them, and Count One should be dismissed as against KVK.

[10] The Third Circuit's decision in *United States v. Sain*, 141 F.3d 463 (3d Cir. 1998), does not hold otherwise. In that case, the court held that a corporation could be held vicariously liable for the conspiracies of its agents only where an agent conspired with "another individual." *Id.* at 475. But *Sain* does not address whether that "[]other individual" can simply be another agent of the corporation. *See, e.g., United States v. Carroll*, 144 F. Supp. 939, 942 (S.D.N.Y. 1956) ("It is true that corporations often have been held to be parties to a conspiracy. However, in all such cases, one corporation had been in concert with another or *with individuals who were not members of the corporation*.") (emphasis added) (citation omitted).

III. The Mail Fraud Charge Is Fatally Defective Also Because, as a Matter of Law, KVK Did Not Conceal Any Material Facts.

A. As a Matter of Law, KVK Did Not Engage in a Scheme to Defraud.

In addition to resting atop an unsound regulatory foundation, the mail fraud charge must be dismissed because the public record of KVK's disclosures forecloses, as a matter of law, the allegation that KVK concealed its use of DRL material from its customers. *See* Indictment at 15 ¶ 4. An essential element of mail fraud is a fraudulent misrepresentation or omission. *See Pearlstein*, 576 F.2d at 535. Therefore, as a matter of law, there can be no fraud where a company proactively discloses the true state of affairs to the other party. *See Lesavoy Found. v. Comm'r*, 238 F.2d 589, 592 (3d Cir. 1956) (holding there was no fraud where the "taxpayer fully disclosed the information required by the informational return"); *Burke v. TV Guide Mag. Grp., Inc.*, 442 F. App'x 356, 358 (9th Cir. 2011) (holding there was no fraud as a matter of law where the defendant "plainly disclose[d] that double and special issues would be counted as two issues"); *Smith v. Grundy Cnty. Nat'l Bank*, 635 F. Supp. 1071, 1076–77 (N.D. Ill. 1986) (holding that there was no mail fraud where the relevant information was "disclosed in *advance* to the [Plaintiffs] in two letters").

The government's mail fraud charge against KVK ignores this basic principle. It is a matter of public record, subject to judicial notice, that in December 2013 KVK issued a voluntary recall for hydroxyzine that disclosed the very information to its customers that the Indictment alleges KVK concealed. *See Lamont*, 236 F.2d at 316-17. As described in an FDA Enforcement Report, on December 11, 2013, KVK recalled all three strengths of hydroxyzine, citing "Good Manufacturing Practices Deviations: The product has an Active Pharmaceutical Ingredient from an unapproved source." *See* FDA, Enforcement Report, *supra*; *see also United States v. Pitt-Des Moines, Inc.*, 970 F. Supp. 1346, 1349 (N.D. Ill. 1997) (observing, in context of motion to dismiss

an indictment, that "the court may take judicial notice of matters of public record"); *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 413 n.16 (D. Del. 2014) (taking judicial notice of document "included in a database maintained by the FDA in the normal course of business"). KVK's recall notice, which went to all affected customers, *see* 21 C.F.R. § 7.49(a), was even more detailed. It explained:

> KVK-Tech, Inc. has initiated this voluntary recall because the firm noted a regulatory filing requirement for the API that is shipped from UCB Pharma S.A., Belgium but manufactured for UCB Pharma S.A. at Dr. Reddy's Laboratories in Mexico instead of the approved manufacturing site in the ANDA i.e. UCB Pharma S.A. located in Belgium.

See Exs. A–C. Thus, more than three weeks before "Customer 1," AmerisourceBergen, allegedly paid $393.97 for hydroxyzine manufactured with DRL material, *see* Indictment at 15–16 ¶¶ 4–5, KVK had disclosed to AmerisourceBergen—along with all KVK's other customers—the exact regulatory issues that the Indictment alleges KVK concealed. Because the public record conclusively shows that AmerisourceBergen was not defrauded, the mail fraud count must be dismissed.

B. The Government Cannot Establish Materiality.

For similar reasons, the government cannot establish that the information KVK allegedly concealed was material to AmerisourceBergen. "[M]ateriality of falsehood is an element of the federal mail fraud . . . statute[]," *Neder v. United States*, 527 U.S. 1, 25 (1999), and requires the Government to establish that the alleged falsehood has "a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed," *id.* at 16 (alteration in original) (internal quotation marks omitted). In assessing materiality under the False Claims Act, the Third Circuit has recognized that alleged false statements are immaterial to the government's payment decision as a matter of law where the government pays claims despite having knowledge of the alleged falsehood. *See United States ex rel. Spay v. CVS Caremark Corp.*,

875 F.3d 746, 763–65 (3d Cir. 2017) (affirming summary judgment decision in defendant's favor when relator failed to dispute that CMS paid claims despite having knowledge of the allegedly deceitful practices); *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) ("Simply put, a misrepresentation is not 'material to the *Government's payment decision*,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance."). The same principle applies here: The fact that AmerisourceBergen still paid for the hydroxyzine after receiving KVK's recall notice demonstrates that the information KVK allegedly concealed—that it allegedly used unapproved material from DRL to manufacture the drug—was immaterial to its purchase.

AmerisourceBergen's decision reflects the underlying fact that differences between the material from DRL and from UCB itself were irrelevant. Indeed, as FDA itself acknowledged when it approved KVK's supplement for the DRL material in 2014, the API was identical in all material respects. It was made according to the same specifications, through the same processes, and subject to the same controls, testing, and quality assurance. Accordingly, no customers or patients ever complained about the drug's quality, and there were no adverse events or other indications of harm reported in relation to the drug—facts reflected in the government's failure to charge KVK with distributing or conspiring to distribute adulterated drugs.[11]

[11] In fact, the government's prosecution of this count is contrary to its own guidance: "Prosecutions of fraud ordinarily should not be undertaken if the scheme employed consists of some isolated transactions between individuals, involving minor loss to the victims, in which case the parties should be left to settle their differences by civil or criminal litigation in the state courts." U.S. Dep't of Justice, Justice Manual § 9-43.100 (updated Jan. 2020).

CONCLUSION

For the foregoing reasons, the Indictment should be dismissed.

Respectfully submitted,

/s/ *Lisa A. Mathewson*

Lisa A. Mathewson
MATHEWSON LAW LLC
123 S Broad Street, Suite 1320
Philadelphia, PA 19109
(215) 399-9592
lam@mathewson-law.com

Jack W. Pirozzolo (*pro hac vice*)
SIDLEY AUSTIN LLP
60 State Street, 36th Floor
Boston, MA 02109
(617) 223-0304
jpirozzolo@sidley.com

Jeffrey M. Senger (*pro hac vice*)
Amy L. DeLine (*pro hac vice*)
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, D.C. 20005
(202) 736-8000
jsenger@sidley.com
adeline@sidley.com

Counsel to Defendant KVK-Tech, Inc.

December 1, 2021

CERTIFICATE OF SERVICE

I hereby certify that on this date the attached Memorandum of Law in Support of Motion to Dismiss, with Exhibits, was filed electronically through the CM/ECF system, which will serve it electronically on all counsel of record.

December 1, 2021

/s/ *Lisa A. Mathewson*
Lisa A. Mathewson

Exhibit A

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

URGENT VOLUNTARY PRODUCT RECALL: December 9, 2013

Dear Valued Customer:

KVK-Tech, Inc. is voluntarily recalling the following lots of HydrOXYzine Hydrochloride Tablets, USP 25 mg

These lots were distributed between the dates of: 05/06/2011 to 01/29/2013

NDC	Description	Lot	Expiry Date
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10666	Feb-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10733	May-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10789	May-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10790	Jun-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10791	Jun-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10792	Aug-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10983	Sep-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10984	Sep-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10986	Oct-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11034	Nov-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11035	Dec-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11036	Dec-14
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11435	Nov-15
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10666	Feb-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10733	May-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10789	May-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10790	Jun-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10791	Jun-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10792	Aug-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10983	Sep-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10985	Oct-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11034	Nov-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11038	Dec-14
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11435	Nov-15
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10666	Feb-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10733	May-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10789	May-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10791	Jun-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10792	Aug-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10983	Sep-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10985	Oct-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10986	Oct-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	11037	Dec-14
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	11435	Nov-15

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

KVK-Tech, Inc. has initiated this voluntary recall because the firm noted a regulatory filing requirement for the API that is shipped from UCB Pharma S.A., Belgium but manufactured for UCB Pharma S. A at Dr. Reddy's Laboratories in Mexico instead of the approved manufacturing site in the ANDA i.e. UCB Pharma S.A. located in Belgium. .

Please examine your stocks immediately to determine if you have any of the above LOT number(s). If so, discontinue distribution of the lot and promptly return all Hydroxyzine HCl tablets in your possession to our attention as follows:

ATTENTION RETURNED Drug Product – HydrOXYzine Hydrochloride Tablets, USP.
110, Terry Drive,
Newtown, PA 18940

You will be reimbursed the actual amount you paid for the returned drug product inclusive of the postage.

Should you have any questions, please do not hesitate to call our customer service at 215-579-1842.

KVK is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and regret any inconvenience this action may cause.

Enclosed please find a RETURN RESPONSE card immediately to:
110, Terry Drive,
Newtown, PA 18940

This voluntary recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your assistance.

Sincerely,

Ashvin Panchal
Director of Quality

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

Return Response Card

Date: _____

Firm Name _____

☐ We do not have any HydrOXYzine Hydrochloride Tablets, USP 25 mg in stock.

☐ Yes, we have the following quantities of HydrOXYzine Hydrochloride Tablets, USP 25 mg which we have removed from sales for disposition as follows:

- ☐ The following quantities are being returned to KVK-TECH, INC, 110 Terry Drive Newtown, PA 18940.
- ☐ We are holding the following quantities for pick-up by your representative.

NDC	Description	Lot	Expiry Date	Quantity
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10666	Feb-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10733	May-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10789	May-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10790	Jun-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10791	Jun-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10792	Aug-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10983	Sep-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10984	Sep-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	10986	Oct-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11034	Nov-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11035	Dec-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11036	Dec-14	
10702-0011-01	Hydroxyzine HCl Tabs USP 25 mg - 100's	11435	Nov-15	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10666	Feb-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10733	May-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10789	May-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10790	Jun-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10791	Jun-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10792	Aug-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10983	Sep-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	10985	Oct-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11034	Nov-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11038	Dec-14	
10702-0011-10	Hydroxyzine HCl Tabs USP 25 mg - 1000's	11435	Nov-15	

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

NDC	Description	Lot	Expiry Date	Quantity
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10666	Feb-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10733	May-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10789	May-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10791	Jun-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10792	Aug-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10983	Sep-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10985	Oct-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	10986	Oct-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	11037	Dec-14	
10702-0011-50	Hydroxyzine HCl Tabs USP 25 mg - 500's	11435	Nov-15	

□ We have notified following customers who have purchased this product.

Name _____

Address _____

_____

City/State/Zip _____

Signature _____ Date: _____

Exhibit B

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

URGENT VOLUNTARY PRODUCT RECALL: December 9, 2013

Dear Valued Customer:

KVK-Tech, Inc. is voluntarily recalling the following lots of HydrOXYzine Hydrochloride Tablets, USP 10 mg

These lots were distributed between the dates of: 12/31/2012 to 5/31/2013

NDC	Description	Lot	Expiry Date
10702-0010-01	Hydroxyzine HCl Tabs USP 10 mg - 100's	11434	Nov-14

KVK-Tech, Inc. has initiated this voluntary recall because the firm noted a regulatory filing requirement for the API that is shipped from UCB Pharma S.A., Belgium but manufactured for UCB Pharma S. A at Dr. Reddy's Laboratories in Mexico instead of the approved manufacturing site in the ANDA i.e. UCB Pharma S.A. located in Belgium. .

Please examine your stocks immediately to determine if you have any of the above LOT number(s). If so, discontinue distribution of the lot and promptly return all Hydroxyzine HCl tablets in your possession to our attention as follows :

ATTENTION RETURNED Drug Product – HydrOXYzine Hydrochloride Tablets, USP.
110, Terry Drive,
Newtown, PA 18940

You will be reimbursed the actual amount you paid for the returned drug product inclusive of the postage.

Should you have any questions, please do not hesitate to call our customer service at 215-579-1842.

KVK is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and regret any inconvenience this action may cause.

Enclosed please find a RETURN RESPONSE card immediately to:
110, Terry Drive,
Newtown, PA 18940

This voluntary recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your assistance.

Sincerely,

Ashvin Panchal
Director of Quality

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

Return Response Card

Date: _____

Firm Name _____

□ We do not have any HydrOXYzine Hydrochloride Tablets, USP 10 mg in stock.

□ Yes, we have the following quantities of HydrOXYzine Hydrochloride Tablets, USP 10 mg which we have removed from sales for disposition as follows:

- □ The following quantities are being returned to KVK-TECH, INC, 110 Terry Drive Newtown, PA 18940.
- □ We are holding the following quantities for pick-up by your representative.

NDC	Description	Lot	Expiry Date	Quantity
10702-0010-01	Hydroxyzine HCl Tabs USP 10 mg - 100's	11434	Nov-14	

□ We have notified following customers who have purchased this product.

Name _____

Address _____

_____

City/State/Zip _____

Signature _____ Date: _____

Exhibit C

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

URGENT VOLUNTARY PRODUCT RECALL: December 9, 2013

Dear Valued Customer:

KVK-Tech, Inc. is voluntarily recalling the following lots of HydrOXYzine Hydrochloride Tablets, USP 50 mg

These lots were distributed between the dates of: 04/12/2011 to 10/21/2013

NDC	Description	Lot	Expiry Date
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10667	Jan-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10677	Jan-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10679	Jan-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10688	May-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10693	Jul-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10854	Jul-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10942	Sep-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10995	Oct-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	10996	Nov-14
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	11138	Feb-15
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	11139	Feb-15
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	11140	Feb-15
10702-0012-01	Hydroxyzine HCl Tabs USP 50 mg - 100's	11445	Nov-15
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10679	Jan-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10689	Jun-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10941	Sep-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10997	Nov-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10998	Nov-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	10999	Nov-14
10702-0012-10	Hydroxyzine HCl Tabs USP 50 mg - 1000's	11445	Nov-15
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10678	Jan-14
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10689	Jun-14
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10855	Jul-14
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10943	Sep-14
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	11136	Feb-15
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	11137	Feb-15
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	11445	Nov-15

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

KVK-Tech, Inc. has initiated this voluntary recall because the firm noted a regulatory filing requirement for the API that is shipped from UCB Pharma S.A., Belgium but manufactured for UCB Pharma S. A at Dr. Reddy's Laboratories in Mexico instead of the approved manufacturing site in the ANDA i.e. UCB Pharma S.A. located in Belgium. .

Please examine your stocks immediately to determine if you have any of the above LOT number(s). If so, discontinue distribution of the lot and promptly return all Hydroxyzine HCl tablets in your possession to our attention as follows:

ATTENTION RETURNED Drug Product – HydrOXYzine Hydrochloride Tablets, USP.
110, Terry Drive,
Newtown, PA 18940

You will be reimbursed the actual amount you paid for the returned drug product inclusive of the postage.

Should you have any questions, please do not hesitate to call our customer service at 215-579-1842.

KVK is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and regret any inconvenience this action may cause.

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Director of Quality

KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

Return Response Card

Date: _____

Firm Name _____

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KVK-TECH, INC.
110 Terry Drive
Suite 200
Newtown PA 18940

Phone: 215-579-1842
Fax: 215-579-0746

NDC	Description	Lot	Expiry Date	Quantity
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10689	Jun-14	
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10855	Jul-14	
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	10943	Sep-14	
10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	11136	Feb-15	
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10702-0012-50	Hydroxyzine HCl Tabs USP 50 mg - 500's	11445	Nov-15	

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Name _____

Address _____

_____

City/State/Zip _____

Signature _____ Date: _____